

# Monitoring of the Lenalidomide Pregnancy Prevention Programme (PPP) Implementation and Effectiveness in Germany (Lena-PIE Germany)

**First published:** 14/02/2022

**Last updated:** 02/07/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS45747

---

### Study ID

45853

---

### DARWIN EU® study

No

---

### Study countries

 Germany

---

### Study description

Evaluation of the outcome indicator (safety outcome): (i) Immediate follow-up and root-cause analysis of all pregnancy cases in association with an exposition to Lenalidomid AL Hartkapseln or Lenalidomid STADA Hartkapseln in Germany reported to STADA. (ii) Systematic database review in STADA's safety database to ensure that no pregnancy case in association with an exposition to Lenalidomid AL Hartkapseln or Lenalidomid STADA Hartkapseln in Germany was missed. Follow-up and root-cause analysis of missed cases. (iii) Systematic review of EudraVigilance data to identify pregnancy cases in association with an exposition to Lenalidomid AL Hartkapseln or Lenalidomid STADA Hartkapseln in Germany not known to STADA. Data entry and processing in STADA's safety database, follow-up and root-cause analysis of cases not known.

---

### **Study status**

Ongoing

## Research institutions and networks

### Institutions

**STADA Arzneimittel**

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

## Contact details

### **Study institution contact**

Sonja Gomez Perez [Sonja.Gomez-Perez@stada.de](mailto:Sonja.Gomez-Perez@stada.de)

Study contact

[Sonja.Gomez-Perez@stada.de](mailto:Sonja.Gomez-Perez@stada.de)

**Primary lead investigator**

Markus Torben Schweimer

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 06/01/2022

Actual: 06/01/2022

---

**Study start date**

Planned: 18/02/2022

Actual: 18/02/2022

---

**Data analysis start date**

Planned: 18/02/2027

---

**Date of final study report**

Planned: 18/02/2028

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

STADA Arzneimittel AG

## Regulatory

### **Was the study required by a regulatory body?**

Yes

---

### **Is the study required by a Risk Management Plan (RMP)?**

EU RMP category 3 (required)

## Other study registration identification numbers and links

STADA study code: PASS-37480-21-0245

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Not applicable

---

#### **Main study objective:**

The objectives of this study are to identify and follow-up on all pregnancies which occur in association with an exposition to Lenalidomid AL Hartkapseln or Lenalidomid STADA Hartkapseln in Germany, to perform a root-cause analysis for such identified cases, and to identify causes that could indicate a failure or weakness of the PPP.

## Study drug and medical condition

### **Medicinal product name, other**

Lenalidomid AL 2,5 / 5 / 7,5 / 10 / 15 / 20 / 25 mg Hartkapseln, Lenalidomid STADA 2,5 / 5 / 7,5 / 10 / 15 / 20 / 25 mg Hartkapseln

---

### **Medical condition to be studied**

Exposure during pregnancy

## Population studied

### **Age groups**

- Adolescents (12 to < 18 years)
  - Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)
- 

### **Special population of interest**

Pregnant women

---

## Estimated number of subjects

0

## Study design details

### Outcomes

(i) Pregnancy in female patient: conception up to 4 weeks after lenalidomide exposition in female patient, (ii) Pregnancy in female partner of male patient: conception up to 7 days after lenalidomide exposition in male patient.

---

### Data analysis plan

Data analysis will be performed as follows: (i) Single case analysis of all pregnancy cases in association with an exposition to Lenalidomid AL Hartkapseln or Lenalidomid STADA Hartkapseln in Germany reported to or identified by STADA, (ii) Descriptive statistics for summarizing data from pregnancy cases in association with an exposition to Lenalidomid AL Hartkapseln or Lenalidomid STADA Hartkapseln.

## Data management

### ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

## **Data sources (types)**

Other

Spontaneous reports of suspected adverse drug reactions

---

## **Data sources (types), other**

Systematic database review

## Use of a Common Data Model (CDM)

### **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

---

### **Check completeness**

Unknown

---

### **Check stability**

Unknown

---

### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No